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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/230,576	02/02/81	BRUGMANE	J 095337

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EXAMINER	
GOLDBERG J	
ART UNIT	PAPER NUMBER
1251	3

DATE MAILED: 07/20/81

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2/2/81 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

- ☒ Claims 1-19 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☐ Claims _____ have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1-19 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
- ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
- ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
- ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other _____

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Art Unit 125

The Renoux et al reference is cited to show the state of the art.

The Cross-reference paragraph should be brought up today.

The reference relied on by applicants should be made of record including on a notice of art cited by applicant, PTO-1449 form.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claim(s) is(are) directed to the same invention as that claimed in claims 1-3 of applicant's Serial No. 067,505. This is a double patenting rejection.

Claims 4-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of applicant's Serial No. 067,505. Although the claim(s) is(are) not identical they are not patentably distinct from each other because the method of treating neoplastic diseases (parent applicant) and the method of treating a specific neoplastic disease (instant cases) read on each other.

The obviousness type double patenting rejection is a judicially established doctrine based on public policy and is primarily intended to prevent prolongation of monopoly by prohibiting claim(s) in a second patent not patentably distinguishing from

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Art Unit 125

claim(s) in a first patent. In re Vogel and Vogel, 164 USPQ 619.

A timely filed terminal disclaimer filed in this application in accordance with 37 CFR 1.321(b) will obviate this rejection. See MPEP 804.02 and 1490.

Claims 1-19 are rejected under 35 U.S.C. 101 for the reason(s) that there is insufficient evidence of record demonstrating that applicants' compound is effective for treating cancer in humans.

This statute states that whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of Title 35 U.S.C..

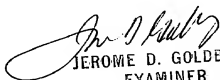
Claims 1-19 are rejected as being based on an insufficient disclosure under 35 USC 112, first paragraph. The term "neoplastic disease" in claim 1 and 2; "pulmonary metastatic tumor" in claim 3; "breast cancer" in claim 4 and 5; "lung cancer" in claims 6 and 7; "malignant melanoma" in claim 8 and 9; "colorectal cancer" in claim 10 and 11; "multiple myeloma" in claims 12 and 13; "head and neck cancer" in claim 14 and 15; "bladder cancer" in claims 16 and 17 and "gastric cancer" in claims 18 and 19 lack clear exemplary support in the specification as filed.

Goldberg:srb

A/C 703

557-2575

7/13/82


JEROME D. GOLDBERG
EXAMINER
GROUP ART UNIT 125

charge the appropriate fee to our deposit account No. 10-750.

The status of Applicants' prior application, serial no. 067,505, has been made of record. Although this parent application is not yet technically abandoned, since the period for Appeal will not expire until December 28, 1982, Applicants intend to allow this parent application to become abandoned by failure to appeal from the decision of the Board of Appeals.

Accordingly, it is believed that all of the rejections on double patenting will be moot by the time the Examiner considers this response.

The rejections of Claims 1-19, all of the claims in the application, under 35 U.S.C. 101 and 35 U.S.C. 112 (first paragraph) are respectfully traversed.

Submitted with this amendment are copies of the primary articles referred to in the W.K. Amery and H. Verhagen article referred to in Applicants' preliminary amendment as reference B1. In view of the decision of the Board of Appeal in Applicants' parent application, it is respectfully submitted that this evidence overcomes the rejections.

To summarize, the Amery article reviews 26 controlled prognostic evaluations of the adjuvant use of levamisole in cancer. These studies are listed in Table 1 and cover evaluations of 1,476 levamisole-treated patients as well as about 1,600 controls. A large variety of cancers were studied, including breast cancer, lung cancer, colon rectal and/or other digestive cancers, lukemias and lymphomas, malignant melanoma, head and neck carcinoma, and bladder cancer. Levamisole has been combined as an adjunct to many different types of primary treatments.